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FLEMINGTON, N.J., June 12, 2002

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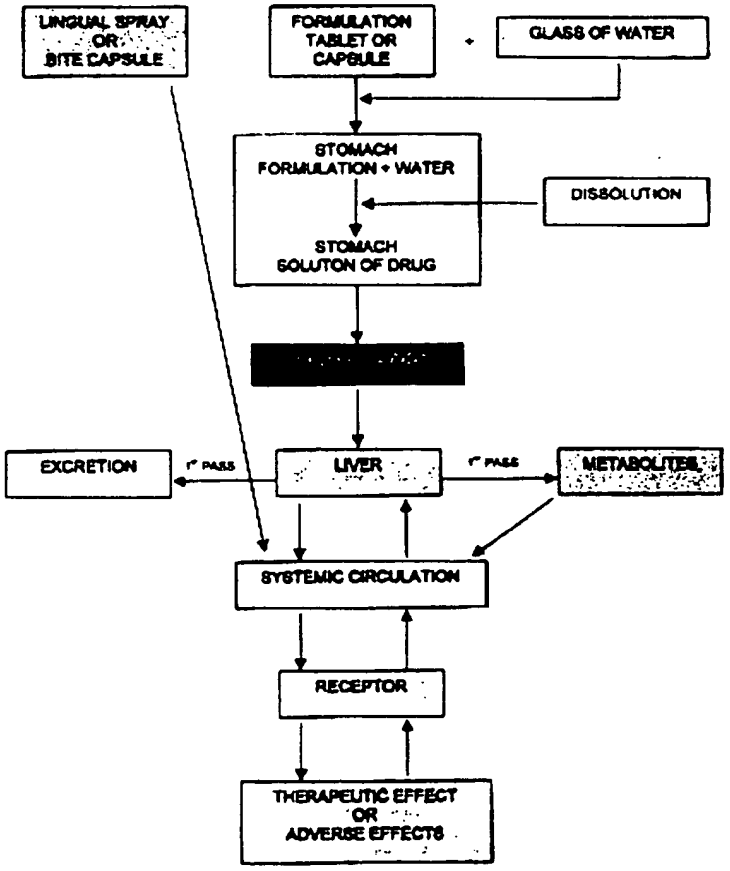
IMMEDIATE-IMMEDIATE RELEASE (I^2R^{TM}) OVERVIEW



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VIEW THE NEW IMMEDIATE-IMMEDIATE RELEASE PRESENTATION

Our technology is called Immediate-Immediate Release (I^2R™) because its delivery systems are designed to provide therapeutic benefits within minutes of administration.

Soft Gelatin Capsule: FPC's soft gelatin capsule formulation consists of a seamless gelatin shell surrounding a core substance (usually a liquid solution). When crushed or chewed, soft gelatin capsules release medication into the mouth, thereby allowing absorption through the oral mucosa. The portion of the dose that is eventually swallowed is introduced to the stomach in a solution ready for immediate absorption, thereby maximizing absorption from the gastrointestinal tract into the bloodstream. The result is rapid onset of the desired therapeutic effect.

Figure 1 shows the improved absorption that can be obtained using a bite capsule as compared to a standard hard gelatin capsule.

FIGURE 1: MEAN PLASMA CONCENTRATIONS OF COMPOUND Y SUBJECTS 1-8

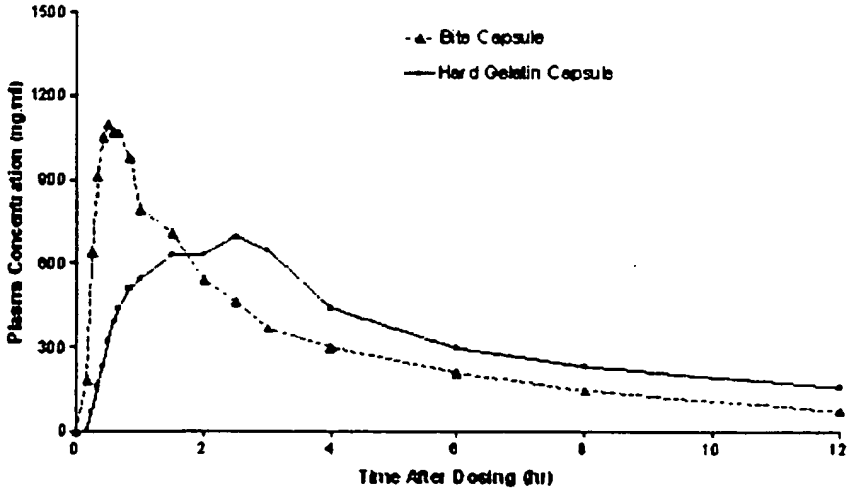
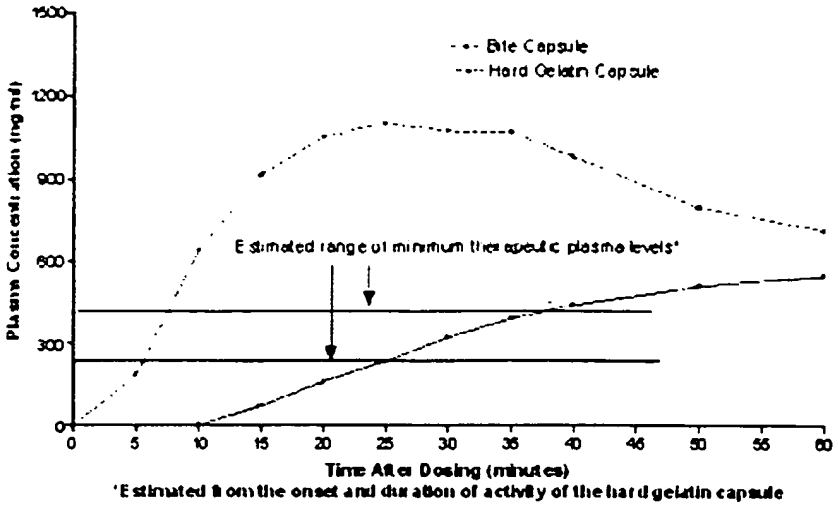


Figure 2 is an expanded view showing the first 60 minutes after dosing. The rapid increase in blood levels will lead to a rapid onset of therapeutic effect.

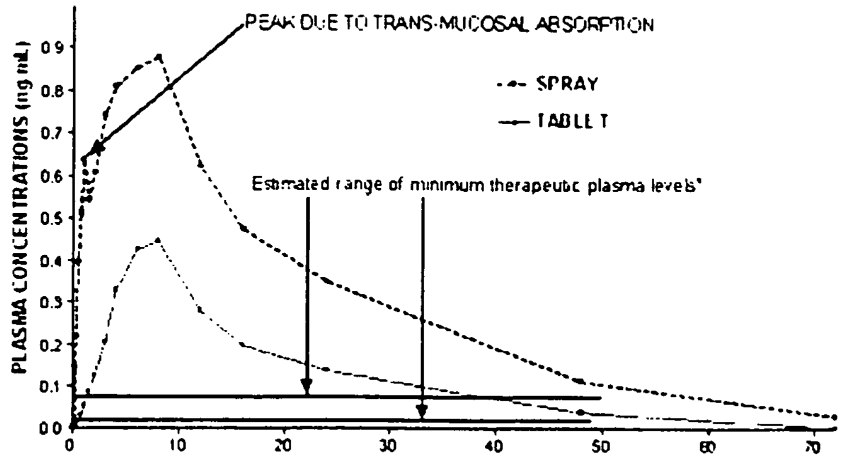
FIGURE 2: MEAN PLASMA CONCENTRATIONS OF COMPOUND Y
SUBJECTS 1-8



Lingual (Oral) Spray: FPC's aerosol and pump spray formulations release the drug in the form of a fine mist into the mouth for immediate absorption into the bloodstream via the mucosal membranes. FPC believes that this dosage form offers certain advantages, including improving the safety profile of certain drugs by lowering the required dosage, improving the dose reliability, and allowing medication to be taken without water. Drug absorption through the mucosal membranes of the mouth is generally rapid, and minimizes the first-pass metabolism effect (i.e., total or partial inactivation of a drug as it passes through the gastrointestinal tract and liver).

Figure 3 shows the improved absorption that can be obtained using an oral spray as compared to a standard tablet.

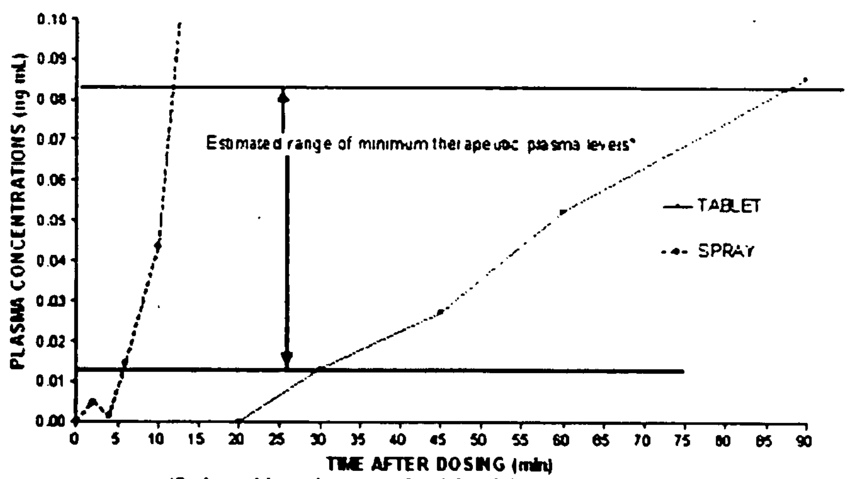
Figure 3: MEAN PLASMA LEVELS OF COMPOUND X
Subject 1-6 and 8



*Estimated from the onset of activity of the tablet (0.5-1.5 hours)

Figure 4 is an expanded view showing the first 90 minutes after dosing. The rapid increase in blood levels will lead to a rapid onset of therapeutic effect.

Figure 4: MEAN PLASMA LEVELS OF COMPOUND X
OBTAINED USING A STANDARD CURVE
0.010-2000 ng/mL



*Estimated from the onset of activity of the tablet (0.5-1.5 hours)

View Drug Products that can be developed with Flemington's Immediate-Immediate Release (I^2R™) Technology More...

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Candidates for Immediate-Immediate Release Technology

This list of products provides examples of applications for our technology. In each case the product could deliver a faster onset of effect with a lower dose. To the extent that side effects are caused by metabolism or metabolites, the lower dose would also lower the side effect profile of the product. There are many products in earlier phases of development that could benefit from this type of formulation and, in particular, products that presently require intravenous administration.

Antihistamines:
clemastine
chlorpheniramine,
dexchlorpheniramine
astemizole
loratadine
combinations with decongestants

Cardiovascular Agents:
nitrates (nitroglycerin)
ACE inhibitors
calcium antagonists
beta blockers

Antidepressants:
fluoxetine (Prozac)
buspirone (Buspar)

Antinauseants:
compazine
chlorpromazine
perphenazine

Biologically Active Amines:
bromocryptine
apomorphine
selegiline
amitriptyline
dopamine precursors
serotonin precursors

Steroids:
testosterone
estradiol
progesterone
combinations of the above

Peptides:
cyclosporine
insulin
calcitonin

Sedatives:
barbituates
benzodiazepines

Sleep Inducers:
temazepam
diphenhydramine
zolpidem
triazolam
nitrazepam

Nutritionals:
vitamins
calcium supplements
iron supplements

Anorexiants:
dextroamphetamine
phentermine
mazindol
sibutramine

Decongestants:
dextromethorphan
pseudoephedrine
phenylpropanolamine

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IMMEDIATE-IMMEDIATE RELEASE (I^2R^{TM})

Flemington Pharmaceutical Corporation (FPC) is engaged in the development of pharmaceutical products incorporating patented and off-patent drugs into oral dosage forms designed to enhance and accelerate the onset of the therapeutic benefits for which the drugs are intended. FPC's development efforts have primarily focused on the application of immediate-release oral dosage forms to specific pharmaceutical substances in order to enhance drug absorption into the body, improve dose reliability, reduce side effects through reduction of the amount of active ingredient required to produce a given therapeutic effect and increase patient convenience and/or compliance. The immediate-immediate release oral dosage forms presently being used by FPC are soft gelatin capsules, and lingual sprays. The development of a product combining a patented, or off-patent drug with a different dosage form generally involves less cost, less time, and less risk than developing and commercializing a new chemical entity.

Just as sustained release formulations have allowed new indications to be claimed, the immediate release technology could allow new uses. As an example, drugs used for long term treatments such as depression probably do not need a fast onset, but if they were used to treat satiety and drug abuse the fast onset would be a big advantage. The product would then be used whenever the urge to abuse food or drugs would arise. With the fast onset formulation, the craving should then subside within minutes for the treatment to be effective.

FPC's patent pending oral dosage forms:

Soft Gelatin Capsule: FPC's soft gelatin capsule formulation consists of a seamless gelatin shell surrounding a core substance (usually a liquid solution). When crushed or chewed, soft gelatin capsules release medication into the mouth, thereby allowing absorption through the oral mucosa. The portion of the dose that is eventually swallowed is introduced to the stomach in a solution ready for immediate absorption, thereby maximizing absorption from the gastrointestinal tract into

the bloodstream. The result is rapid onset of the desired therapeutic effect.

Figure 1 shows the improved absorption that can be obtained using a bite capsule as compared to a standard hard gelatin capsule. Figure 2 is an expanded view showing the first 60 minutes after dosing. The rapid increase in blood levels will lead to a rapid onset of therapeutic effect.

Lingual (Oral) Spray: FPC's aerosol and pump spray formulations release the drug in the form of a fine mist into the mouth for immediate absorption into the bloodstream via the mucosal membranes. FPC believes that this dosage form offers certain advantages, including improving the safety profile of certain drugs by lowering the required dosage, improving the dose reliability, and allowing medication to be taken without water. Drug absorption through the mucosal membranes of the mouth is generally rapid, and minimizes the first-pass metabolism effect (i.e., total or partial inactivation of a drug as it passes through the gastrointestinal tract and liver).

Figure 3 shows the improved absorption that can be obtained using an oral spray as compared to a standard tablet. Figure 4 is an expanded view showing the first 90 minutes after dosing. The rapid increase in blood levels will lead to a rapid onset of therapeutic effect.

Types of drug products best suited to FPC's formulations:

In general, drug products that have a low dose and a high first pass effect are the best candidates for this technology. First pass effect refers to the removal of the drug from the portal blood by biliary excretion or by metabolism on the first pass through the liver after absorption from the stomach or intestine on the way to the systemic blood. Some drugs pass through the liver with very little change while others can be reduced by 80-99% with only 1-20% reaching the circulating blood.

The ideal dosage range for use in a spray that delivers only 50-100 microliters is in the 1-10 mg range. The soft gelatin capsules can delivery more drug -- up to 200 mg. In many cases the amount of drug used in the conventional dosage formulation would seem to preclude the use of this technology. However, with the improved absorption obtained, using FPC's formulations, the dose can often be reduced to a level that will readily allow development of either a bite-gel or lingual spray formulation.

Some candidates for Immediate-Immediate Release (I2RTM)Technology:

The list of products found Table 1 are examples of the possible scope of the application of this technology. In each case the product would deliver a faster onset of effect with a lower dose. To the extent that side effects are caused by metabolism or metabolites, the lower dose would also lower the side effect profile of the product. Less substrate would be available for conversion to metabolites. There are many products in earlier phases of development that could also use this type of formulation and in particular products that presently require intravenous administration. Not every indication would benefit from the fast onset, although the lowering of the dose resulting in a lower number of adverse effects would always be a benefit.

Summary:

Flemington Pharmaceutical Corporation development efforts have primarily focused on the application of immediate-release oral dosage forms. The focus has been on specific pharmaceutical substances in order to enhance drug absorption into the body, improve dose reliability, reduce side effects through reduction of the amount of active ingredient required to produce a given therapeutic effect and increase patient convenience and/or compliance. These formulations are an excellent way to revitalize a product just before patent expiration by changing the dose and modifying the claims to include more rapid onset of action, or for smaller companies to take existing generic drugs and for a much smaller investment obtain a novel proprietary drug. FPC believes that by developing new dosage forms it may expand the market for an existing drug; differentiate the product from off-patent and brand-name competition; and possibly create a new market.